

WHAT IS CLAIMED IS:

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1. A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the steps of:

5 a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of a fusion protein identified as etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human; and  
b) administering said dose either intralesionally or perilesionally.

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15 2. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating Alzheimer's Disease.

3. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed through any of the following

routes: subcutaneous, intrathecal, intramuscular, intranasal, transepidermal, parenteral, transepithelial, or epidural.

4. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating nerve root injury caused by a herniated nucleus pulposus.

5. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating Bell's Palsy.

6. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating Carpal Tunnel Syndrome.

7. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating acute spinal cord injury.

8. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating spinal cord compression.

9. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating spinal stenosis.

10. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating localized disorders of muscle, including muscle spasm, muscle tear, muscle injury, muscle strain, or muscle sprain.

11. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said dosage level is for treating glaucoma.

12. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist is performed subcutaneously in said human wherein said dosage level is in the range of 1mg to 300mg per dose.

13. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed intramuscularly in said human wherein said dosage level is in the range of 1mg to 100mg.

14. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed subcutaneously in said human wherein said dosage level is in the range of 1mg to 100mg.

15. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of etanercept is performed subcutaneously in said human wherein said dosage level is in the range of 10mg to 25mg.

16. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of D2E7 is performed subcutaneously in said human, wherein said dosage level is in the range of 1mg to 100mg.

17. A method for inhibiting the action of TNF in accordance with Claim 1, wherein the step of administering said TNF antagonist in the form of D2E7 is performed subcutaneously in said human, wherein said dosage level is in the range of 10mg to 40mg.

18. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of etanercept, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

19. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of etanercept, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose subcutaneously to the area anatomically adjacent to the site of disc herniation.

20. A method for inhibiting the action of TNF in accordance with Claim 19, wherein the step of administering said dosage level is for treating nerve root injury due to a herniated nucleus pulposus, wherein the dosage level is between 1mg and 100mg.

21. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

5 a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

22. A method for inhibiting the action of TNF for treating glaucoma in a human by administering a TNF antagonist for reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human, comprising the step of:

15 a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized

monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for treating glaucoma by reducing the inflammation of the optic nerve or retina of said human, or for modulating the immune response affecting the optic nerve or retina of said human.

5 <sup>20</sup>~~23~~. A method for inhibiting the action of TNF in accordance with Claim <sup>19</sup>~~22~~, wherein the step of administering said TNF antagonist is performed through any of the following routes: subcutaneous, intranasal, transepidermal, parenteral, or transepithelial.

10 24. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of etanercept, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

15 b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

25. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

5 a) administering a therapeutically effective dosage level to said human of D2E7, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

26. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

15 a) administering a therapeutically effective dosage level to said human of infliximab, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and



b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

27. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of CDP 870, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

28. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of CDP 571, for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

29. A method for inhibiting the action of a cytokine for treating a pathologic condition in a human, the pathologic condition being a disease or disorder which is caused or exacerbated by the action of the said cytokine by administering a cytokine antagonist, defined as any of the following types of molecules directed against the said cytokine: a monoclonal antibody; a monoclonal antibody fragment; soluble receptors; or a fusion protein, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of said cytokine antagonist; and

b) administering said dose either intralesionally or perilesionally.

30. A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal

tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of a fusion protein identified as etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human.

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31. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said dosage level is for treating Alzheimer's Disease.

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32. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said dosage level is for treating glaucoma.

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33. A method for inhibiting the action of TNF in accordance with Claim 30, wherein the step of administering said dosage level is for treating Postherpetic Neuralgia.

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34. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

5 a) administering a therapeutically effective dosage level to said human of a soluble TNF receptor Type I for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

35. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

15 a) administering a therapeutically effective dosage level to said human of a pegylated soluble TNF receptor Type I for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

36. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of a molecule containing at least one soluble TNF receptor for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose perilesionally by subcutaneous administration in the lumbar area (for lumbar or sacral nerve roots) or in the cervical area (for cervical nerve roots).

37. A method for inhibiting the action of TNF for treating or preventing nerve root injury in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

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a) administering a therapeutically effective dosage level to said human of said TNF antagonist consisting of a molecule which contains a fragment of any of the molecules selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

38. A method for inhibiting the action of TNF for treating or preventing nerve root injury caused by a herniated nucleus pulposus in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said nerve root of said human, comprising the steps of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), a molecule containing a soluble TNF receptor, a molecule containing multiple soluble TNF receptors, and a

molecule which contains a fragment of any of the above molecules for reducing the inflammation of said nerve root of said human, or for modulating the immune response affecting neuronal tissue of said human; and

b) administering said dose either intralesionally or perilesionally.

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